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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/037,460	03/10/1998	GREGG A. HASTINGS	325800-626(P)	7163

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/15/2002

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/037,460

Applicant(s)

HASTINGS et al.

Examiner

Christine Saoud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 7, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-67, 75-92, 102-107, 115-119, and 122-175 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-67, 75-92, 102-107, 115-119, and 122-175 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 33 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claim 176 has been canceled as requested in the amendment of paper #32, filed 07 May 2002. Claims 54-67, 75-92, 102-107, 115-119, and 122-175 are pending in the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed 07 May 2002 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 101

5. Claims 54-67, 75-92, 102-107, 115-119 and 122-175 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for the reasons of record in paper #20, 24 and 31. The instant application has provided a description of an isolated DNA encoding a protein and the protein

encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

Applicant argues that the specification teaches that the claimed protein has use “to proliferate vascular smooth muscle and endothelial cells...; as a tumor diagnostic...; and/or to accelerate the mitogenic activity of other growth factors...” First, the specification at page 24, first paragraph, does not support a use to “accelerate the mitogenic activity of other growth factors”. The specification at page 24 asserts that “VIGF in combination with other growth factors including but not limited to, PDGF, IGF, FGF, EGF or TGF- β may accelerate physiological responses as seen in wound healing”, which is not the same as what Applicant argues at page 2 of the response. Secondly, there is no evidence of record to support any of the asserted uses of the instant specification and one of ordinary skill in the art would not find any of the asserted uses of the specification specific, substantial and credible for the reasons of record.

Applicant asserts that the specification describes the function of VIGF. This assertion is not persuasive, because although the specification asserts a function for the disclosed protein, this assertion is not based on any facts or evidence to support such a conclusion. As indicated in the previous Office actions, a conclusion of biological activity based on amino acid structure alone is not sufficient to support such an assertion because the prior art establishes that amino acid structure alone is not predictive of function. Applicant cites Bechard et al. (J. Biol. Chem 276(51): 48341-48349, 2001) for a teaching that the claimed protein “is useful as a tumor diagnostic, and to enhance the proliferation of endothelial cells associated with tissue regeneration and angiogenesis”. This conclusion is not consistent with the teachings of Bechard et al. and the

assertions of the instant specification. First, Bechard et al. (J. Immunol. 167: 3099-3106, 2001) teach that ESM-1 (identical to the claimed protein) is found in sera from healthy subjects and is increased in patients with acute and severe sepsis (see page 3099, column 2, paragraph 2). Based on this teaching, the assertion that the protein could be used as a diagnostic for cancer is not credible. The protein is found in healthy individuals, is elevated in another disease state, and there is no evidence that any particular level or amount is diagnostic of any particular type of cancer. The instant specification fails to provide a use for the protein in a currently available form for use as a tumor diagnostic, absent evidence to the contrary. The statement of Bechard et al. that ESM-1 “may” regulate tumor progression does not support a use as a tumor diagnostic because neither the instant specification nor the prior art provides a necessary correlation or nexus between the claimed protein and any tumor which would be required for use of the claimed protein in a diagnostic capacity.

With regard to the assertion that the claimed protein is useful “to enhance the proliferation of endothelial cells”, this is not an asserted use in the instant specification. Bechard et al. (J. Biol. Chem.) demonstrates that the claimed protein does not stimulate cell proliferation alone (see page 48347, column 1, lines 12-15). Bechard et al. teach that the claimed protein can enhance HGF/SF (hepatocyte growth factor/scatter factor) cell proliferation, but this is not asserted in the specification and the relationship of HGF/SF and the claimed protein would be an essential feature for use to stimulate cell proliferation. The assertion in the instant specification that the claimed protein “in combination with other growth factors including but not limited to, PDGF, IGF, FGF, EGF or TGF- β may accelerate physiological responses as seen in wound healing” does not

provide a specific, substantial and credible utility for the claimed protein because it fails to provide the essential feature that the claimed protein will not stimulate cell proliferation on its own, but will enhance cell proliferation which is stimulated by HGF/SF.

Applicant argues that “[a]ll that is required of Applicants is that there be a reasonable correlation between the biological activity and the asserted utility”, however, as pointed out above, there is not a reasonable correlation between the asserted uses and the activities which are described by the Bechard et al. references. There is no evidence that the claimed protein could be used as a tumor diagnostic, or that the protein alone can be used to proliferate vascular smooth muscle and endothelial cells. Since the claimed protein fails to stimulate proliferation of cells on its own and will only stimulate the cells in the presence of HGF/SF, and this information is not provided in the specification, the invention as claimed was not useful at the time the specification was filed, and therefore, lacks utility for proliferation of vascular smooth muscle and endothelial cells, absent evidence to the contrary.

It is believed that the Examiner has rebutted Applicant’s arguments and has established reasons and evidence why a rejection for lack of utility is proper.

6. Claims 54-67, 75-92, 102-107, and 115-119, and 122-175 are rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. §101 for the reasons of record in papers #20, 24, and 27.

Applicant argues that because the invention has utility, then this rejection should be withdrawn as well. This argument is not persuasive for the reasons provided above, and therefore, is maintained.

Conclusion

7. No claim is allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Thursday from 8AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud